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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/589,957

08/18/2006

Aida Inbal

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EXAMINER

ROOKE, AGNES BEATA

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

03/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/589,957	Applicant(s) INBAL ET AL.	
	Examiner Agnes B. Rooke	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/18/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Claims 9-24 are pending and currently under consideration. Claims 1-8 are cancelled.

Priority

2. This application is a 371 of PCT/EP05/01495 filed on 02/15/2004, which claims foreign priority to EUROPEAN PATENT OFFICE (EPO) 04003950.5 filed on 02/20/2004. The priority is awarded to the aforementioned applications.

IDS

3. The Information Disclosure Statement filed on 08/18/2006 has been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action.

Drawings

4. The Drawing submitted on 08/18/2006 are accepted by examiner.

Objection to Specification

5. The specification is objected to because of the following informalities:
(a) the content of the specification is missing, i.e. the Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11. The priority information should be included in the first paragraph of the specification.

Correction of the above is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 9-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Deisher et al. (WO 98/51333, international publication date 19 Nov, 1998; the reference is listed on the IDS document submitted on 08/18/2006).

Deisher et al. teach methods and compositions useful in treatment of reducing ischemic reperfusion injury and reducing necrotic tissue damage and/or vascular injury resulting from ischemic reperfusion by administration of factor XIII. See Example 1, and page 1, lines 9-16 (instant claims 9, 11, 14, 16, and claims 19-24 in reference to diseases to be treated that are characterized by the presence of ischemic tissue, i.e. obstruction of the blood flow).

Deisher et al. teach methods for reducing ischemic reperfusion injury, reduction in tissue damage, vascular injury, myocardial infarction or stroke in a patient, wherein an effective amount of factor XIII is administered to a patient; and where the ischemic reperfusion injury addresses all diseases which are associated with disturbed blood perfusion and thus include instant claims that refer to stimulating the perfusion of ischemic tissues. See page 7, lines 25-28; page 9, lines 24-29; and page 11, lines 2-3; page 7, lines 10-17 (instant claims 9, 11, 14, 16, and 19-24 where all the diseases claimed suffer from disruption of a blood flow to the tissue, i.e. ischemia, for example).

Deisher et al. teach that the factor XIII composition is administered to the patient as a bolus injection. See page 7, lines 28-31 (instant claims 9, 11, 12, 14, 16, 17).

Deisher et al. teach that that the factor XIII composition can be administered as gels, foams or bandages [thus topical administration]. See page 8, lines 5-7 (instant claims 10, 13, 15, 18).

Further, the phrase in claims 9 and 14 in reference to a method of "stimulating the perfusion of ischemic tissues" is an intended use and it is not a limitation to the instant one step method. For, example, the court stated that the claim preamble must be read in the context of the entire claim. The determination of whether preamble recitations are structural limitations or mere statements of purpose or use "can be resolved only on review of the entirety of the [record] to gain an understanding of what the inventors actually invented and intended to encompass by the claim." *Corning Glass Works*, 868 F.2d at 1257, 9 USPQ2d at 1966. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation"). See MPEP 2111.02.

Therefore, in the instant case, the phrase “stimulating the perfusion of ischemic tissues” is only stating the purpose or the intended use for the invention, and it is not a claim limitation.

Therefore, the claims are anticipated.

References of interest:

8. Dardik et al., “*Novel Proangiogenic Effect of Factor XIII Associated With Suppression of Thrombospondin 1 Expression*”, *Arterioscler. Thromb. Vasc. Biol.* 2003, 23, pages 1472-1477, (this reference is cited on the IDS document submitted on 08/18/2006), teach that factor XIII participates in tissue remodeling and wound healing, and processes that involve angiogenesis, where in vivo or in vitro models were used to examine the role of factor XIII in angiogenesis, i.e, migration, proliferation of cells. See page 1447, left column, third paragraph; page 1475, left column, second paragraph; and see *Discussion* section on page 1476. This reference does not specifically teach the treatment for stimulating the perfusion of ischemic tissues.

Kato et al. (WO 94/22470) teach dermal preparation for treatment of skin wounds containing as an active ingredient human blood coagulation factor XIII; where the dermal preparation can be applied to the skin as effective delivery of factor XIII. (See Abstract and page 1 of the specification, for example).

Conclusion

9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

AR

/Kathleen Kerr Bragdon/

Supervisory Patent Examiner, Art Unit 1656